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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,882	06/21/2006	Anthony Martin	15568.28	8754

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EXAMINER	
JOYNER, KEVIN	
ART UNIT	**PAPER NUMBER**
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,882	MARTIN, ANTHONY	
	Examiner	Art Unit	
	KEVIN C. JOYNER	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-22* is/are pending in the application.

4a) Of the above claim(s) *22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 5, 2009 has been entered.

Election/Restrictions

2. Newly submitted claim 22 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The apparatus as claimed may be used to practice a materially different method. More specifically, the apparatus may be used to practice a method wherein the pumps are operated in alternate fashion to spray a vaporous coating onto an item in the enclosure.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 22 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. More specifically, the operation to be carried out comprises process steps that do not take place in the main chamber. For example, a means for rendering the sterilant ineffective is located in a conduit that is not located in the main chamber. Therefore, the specification does not support the limitation that this particular limitation is carried out in the main chamber.

5. Claims 16 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. More specifically, the specification does not support the claim limitations that the main chamber is capable of being sealed closed. Appropriate action is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 3, 4, 6, 7, 10, 11 and 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drinkwater (International Publication No. WO 02/11774) in view of Hunter et al. (U.S. Patent No. 6,368,206) and Adams (International Publication No. WO 03/082355).

Drinkwater discloses an enclosure 10 for carrying out an operation under sterile conditions, the enclosure comprising:

A main chamber;

A plenum chamber;

A filter 11 separating the plenum chamber from the main chamber;

A pump 18 for the plenum chamber and capable of delivering air into the plenum chamber and then through the filter to the main chamber to create a filtered flow of air through the main chamber; and

A means for drawing gas from the enclosure 10 via an outlet that comprises a fan 16 located in a conduit connected to the outlet that is capable of creating a flow of sterilant vapor; and

Wherein the conduit has means 31 for rendering sterilant flowing through the conduit ineffective to avoid release of sterilant to the atmosphere as set forth in pages

3-5. More specifically, the reference discloses that the flow of gas is vertical through the enclosure (page 3, lines 25-30), wherein the outlet is located on the base of the enclosure. However, the reference also suggests that the outlet that extracts gases from the enclosure may also be placed on another face of the enclosure (i.e. the face of the enclosure corresponding to the plenum chamber; page 3, lines 35-37).

Hunter discloses an enclosure for carrying out an operation under sterile conditions comprising a main chamber and a plenum chamber with a filter separating the main chamber from the plenum chamber as well as a pump and an outlet located in the plenum chamber (column 6, lines 55-68). As shown in Figures 3 and 4, the pump 28 is fully capable of delivering air into the plenum chamber and then through the filter to the main chamber to create a filtered flow of air through the main chamber; and the exhaust is disclosed as being configured with an exhaust system (column 11, lines 37-45; such as the system of Drinkwater) in a manner such that gas is drawn from the enclosure via an outlet 124 from the plenum chamber 33, capable of creating a flow of sterilant vapor from the main chamber 44 through the filter 32 to decontaminate the filter and through the plenum chamber to the outlet to sterilize the plenum chamber before exiting the outlet and to maintain a pressure in the main and plenum chambers below atmospheric so that any leak paths result in leakage from the atmosphere into the chambers and do not result in release of sterilant vapor to the atmosphere around the enclosure. More specifically, Hunter provides motivation to configure the outlet in the plenum chamber of Drinkwater. The motivation is provided in column 4, lines 50-56 that discloses such an exhaust system reduces undesired blower loading, makes better

utilization of available filter surface area and is readily accessible. As such, placing the exhaust outlet of Drinkwater in the plenum chamber would reduce undesired blower loading, make better utilization of available filter surface area and be readily accessible; wherein such a configuration would provide a means for drawing gas from the enclosure via the outlet from the plenum chamber that is capable of creating a sterilant flow from the main chamber through the filter to decontaminate the filter and through the plenum chamber to the outlet that would maintain pressure in the main and plenum chambers below atmospheric so that any leak paths result in leakage from the atmosphere into the chambers and do not result in release of sterilant vapor to the atmosphere around the enclosure. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to place the exhaust outlet of Drinkwater in the plenum chamber as exemplified by Hunter to produce an exhaust system that reduces undesired blower loading, makes better utilization of available filter surface area and is readily accessible as exemplified by Hunter.

Drinkwater discloses an apparatus that generates and delivers a sterilant vapor to the main chamber to sterilize the enclosure (page 5, lines 1-20), but does not disclose that the apparatus is located within the main chamber. Adams discloses an enclosure for carrying out an operation under sterile conditions, wherein the enclosure comprises a first apparatus disposed within the enclosure for generating and delivering a sterilant vapor from a supply held within the main chamber to be distributed throughout the enclosure to sterilize the surfaces of the enclosure (Figure 11). The sterilant apparatus provided in the enclosure increases the efficiency of the apparatus

and is considerably less expensive (page 6, lines 5-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Drinkwater to include an apparatus disposed within the enclosure for generating and delivering a sterilant vapor from a supply held within the main chamber to be distributed throughout the enclosure to sterilize the surfaces of the enclosure in order to increase the efficiency of the apparatus and utilize an apparatus that is considerably less expensive as exemplified by Adams.

With regard to claim 3, absent unexpected results, it would have been obvious to one of ordinary skill in the art at the time of the invention to locate the means for rendering the sterilant ineffective 31 upstream of the fan 16, as such would be no more than a matter of engineering choice. Furthermore, the claim defines a rearrangement of the fan with respect to the means for rendering the sterilant ineffective. In *In re Japikse,* 181 F.2d 1019, 86 USPQ 70 (CCPA 1950), the courts held that where the only difference between the prior art and the claimed invention was a rearrangement of parts that did not modify the function or operation of the apparatus was deemed to be held unpatentable (See MPEP 2144.04). Accordingly, the claimed arrangement of the fan with the means for rendering the sterilant ineffective is considered to be not patentably distinct from the disclosed Drinkwater disclosure. Concerning claim 4, Drinkwater continues to disclose that the means for rendering the sterilant ineffective comprises a catalytic converter for breaking the sterilant down into harmless biproducts (page 3, lines 12-18).

Concerning claim 6, the operation of Adams is carried out in the main chamber of the enclosure (Figure 11). Therefore, the operation to be carried out under sterile conditions of Drinkwater in view of Adams will also be performed in the main chamber. Concerning claim 7, Drinkwater discloses a filter 12 that is provided in the outlet. Concerning claim 10, Drinkwater and Hunter disclose an exhaust filter (12 of Drinkwater; 30 of Hunter) located at the outlet through which the air/sterilant vapor is drawn from the chamber. With regard to claim 11, the Manual of Patent Examining Procedures discloses that in *In re Harza,* 274, F.2d 669, 124 USPQ 378 (CCPA 1960), a mere duplication of parts for a multiplied effect has no patentable significance unless a new and unexpected result is produced (See MPEP 2144.04). As such, the two filter configuration of claim 11 is not patentably distinguishable from Drinkwater in view of Hunter.

With regard to claim 13, Drinkwater discloses a filter 25 provided in the conduit connected to the outlet from the chamber (Figure 1). Concerning claim 14 and 15, Although Hunter does not appear to disclose that the filter separating the main and plenum chambers is a HEPA and air filter, such filters are extremely well known and thus conventional and commercially available in the art. One such example is provided in Hunter wherein the reference discloses that a HEPA filter is utilized to filter the main chamber from contaminants and particulates (column 7, lines 30-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize a HEPA filter to separate the main chamber from the plenum chamber in order to filter the main chamber from particulates and contaminants as exemplified by Hunter.

Concerning claim 16, Drinkwater also discloses that the main chamber is sealed closed except that gas can travel in and out of the main chamber through the filter separating the main chamber from the plenum chamber (page 2, lines 1-5).

With regard to claims 17-21, the limitations are met with respect to claims 1 and 14-16 above. Therefore, their explanations are relied upon as necessary. Furthermore, concerning the limitations of the pumps' operation, the Manual of Patent Examining Procedures specifically states that, "while the features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function" as well as, "a claim containing a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all the structural limitations of the claim." (MPEP 2114 [R-1]).

8. Claims 5 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drinkwater (International Publication No. WO 02/11774) in view of Hunter et al. (U.S. Patent No. 6,368,206) and Adams (International Publication No. WO 03/082355) as applied to claims 3 and 4 above, and further in view of McClure (U.S. Patent No. 4,601,885).

Drinkwater in view of Hunter and Adams is relied upon as set forth above. Regarding claims 5 and 12, Drinkwater in view of Hunter and Adams does not appear to disclose that the conduit has selectively operable valve controlled outlets of larger and smaller capacities, the smaller capacity outlet being open during said period when the

enclosure is to be maintained at a predetermined reduced pressure and the larger valve controlled outlet being opened during discharge of the sterilant atmosphere from the enclosure. McClure discloses a sterilization system for an enclosure that includes and outlet to relieve pressure from within the system (column 2, lines 15-24). The reference continues to disclose that the outlet has selectively operable valve controlled outlets of larger and smaller capacities, the smaller capacity outlet (41) is capable of being open during a period when the enclosure is to be maintained at a predetermined reduced pressure and the larger valve (38) is capable of being opened during discharge of the sterilant atmosphere from the enclosure (column 4, lines 1-35; Figure 2). McClure also discloses that the valves are utilized in order to control the pressure throughout the system. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the outlet conduit of Drinkwater to include selectively operable valve controlled outlets of larger and smaller capacities, the smaller capacity outlet is capable of being open during a period when the enclosure is to be maintained at a predetermined reduced pressure and the larger valve is capable of being opened during discharge of the sterilant atmosphere from the enclosure in order to accurately control the pressure throughout the system as exemplified by McClure.

9. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drinkwater (International Publication No. WO 02/11774) in view of Hunter et al. (U.S. Patent No. 6,368,206) and Adams (International Publication No. WO 03/082355) as applied to claim 1 above, and further in view of Morrow et al. (U.S. Patent No. 2002/0168305).

Drinkwater is relied upon as set forth in reference to claim 1. Drinkwater does not appear to disclose that the enclosure contains a second apparatus comprising a housing containing a catalytic converter for converting the sterilant into harmless byproducts for disposal and means for circulating the atmosphere of the chamber through the housing to reduce the sterilant concentration in the atmosphere when the sterilization operation has been performed. Morrow discloses an apparatus for use in an enclosure that is capable of rendering sterilant in the atmosphere in a chamber ineffective (paragraphs 2 and 46-49). The reference continues to disclose that the apparatus contains a housing (12) containing a catalytic converter (paragraph 57) capable of converting the sterilant into harmless byproducts for disposal and means (20) for circulating the atmosphere of the chamber through the housing capable of reducing a sterilant concentration in the atmosphere when a sterilization operation has been performed. The second apparatus is utilized to provide an airstream free from contamination and other elements harmful to people. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Drinkwater to include a second apparatus comprising a housing containing a catalytic converter capable of converting the sterilant into harmless byproducts for

disposal and means for circulating the atmosphere of the chamber through the housing capable of reducing a sterilant concentration in the atmosphere when a sterilization operation has been performed in order to provide an airstream free from contamination and other elements harmful to people as exemplified by Morrow.

Response to Arguments

10. Applicant's arguments with respect to claims 1 and 3-21 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEVIN C. JOYNER whose telephone number is (571)272-2709. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth L McKane/
Primary Examiner, Art Unit 1797

KCJ